NUTRI.018RA PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application for Reissue of:		
Applicant	:	Mark F. McCarty
U.S. Patent No.:	:	5,929,066
Appl. No.	:	09/110,511
Issued	:	February 2, 1999
For		CHROMIUM/BIOTIN TREATMENT OF TYPE II DIABETES

REISSUE PRELIMINARY AMENDMENT AND STATEMENT UNDER 37 C.F.R. 1.173(C)

Assistant Commissioner for Patents
Washington, D.C. 20231

Dear Sir:

The following amendments are made pursuant to 37 C.F.R. § 1.173(b)(2). Prior to examination of the above-identified Reissue Application, please amend the reissue application as follows:

IN THE CLAIMS

Kindly add claims 11 through 24 as follows:

11. A method for reducing hyperglycemia or stabilizing the level of serum glucose comprising administering to an individual in need thereof between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 μg and 200 mg per day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

12. A method for reducing hyperglycemia or stabilizing the level of serum glucose comprising administering to an individual in need thereof a composition consisting essentially of between about 50 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate in combination with between about 25 micrograms and 200 milligrams per day of biotin, wherein the

amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

13. The method of claim 12, wherein the individual is a human.

14. The method of claim 12, comprising administering between about 500 and 1,000 micrograms per day of chromium as synthetic chromic tripicolinate.

15. The method of claim 12, comprising administering between about 1 milligram and 100 milligrams biotin per day.

16. The method of claim 12, comprising administering about 600 micrograms of chromium as synthetic chromic tripicolinate and about 300 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

17. The method of claim 12, comprising administering about 400 micrograms of chromium as synthetic chromic tripicolinate and about 200 micrograms of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

18. The method of claim 12, wherein said chromic tripicolinate is in a pharmaceutically acceptable carrier.

19. The method of claim 12, wherein said biotin is in a pharmaceutically acceptable carrier.

20. The method of claim 12, wherein said chromic tripicolinate is orally administered.

21. The method of claim 12, wherein said biotin is orally administered.

22. The method of claim 12, wherein said chromic tripicolinate is parenterally administered.

23. The method of claim 12, wherein said biotin is parenterally administered.

24. A pharmaceutical composition consisting essentially of chromium as synthetic chromic tripicolinate and biotin, wherein the ratio of chromium to biotin is between about 2:1 and 1:200 (w/w), wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

25. A pharmaceutical composition comprising about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

26. A pharmaceutical composition consisting essentially of about 600 micrograms/day of chromium as synthetic chromic tripicolinate and about 300 micrograms/day of biotin, wherein the amounts of chromic tripicolinate and biotin are selected together to provide a greater than additive effect.

REMARKS

The following comments are made to comply with 37 C.F.R. § 1.173(c). Claims 1-24 are pending in the reissue application. Claims 11 through 24 have been added as set forth above.

In accordance with 35 U.S.C. § 251, which requires that the error upon which a reissue is based be one which causes the patent to be "deemed wholly or partly inoperative or invalid, by reason of the patentee claiming more or less than he had a right to claim in the patent," the Applicant intends to broaden some of the claims of the instant reissue application and narrow others. Specifically, Applicant requests reissue of the above-referenced patent in order to add a claim that does not require both a reduction in hyperglycemia and the stabilization of the serum glucose level in an individual. Additionally, Applicant requests reissue of the above-referenced patent in order to add claims that exclude compositions having other active blood glucose serum ingredients.

No other changes have been made and no new matter is added. Support for the amendment is found throughout the specification in general, and specifically on column 3, lines 7-13 of the issued U.S. Patent No. 5,929,066. Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410. A duplicate copy of this sheet is enclosed.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 7/24/01

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